HOT TODDY

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

HOT TODDY™ ADULT SACHETS powder for oral solution

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (african ginger), Hedera helix L. (ivy extract), ascorbic acid (vitamin C), Citrus limon (L.) Osbeck (lemon), honey, Zingiber officinale Roscoe (ginger), Cinnamomum cassia (L.) J. Presl. (cinnamon). Contains sugar: Each sachet contains 3 927 mg sucrose.

Contains sweetener: Each sachet contains 43 mg Sweetener A100 (containing acesulfame K and sodium cyclamate).

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.

HOT TODDY™ ADULT SACHETS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take HOT TODDY™ ADULT SACHETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask you pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

- What HOT TODDY™ ADULT SACHETS is and what it is used for.
- What you need to know before you take HOT TODDY™ ADULT SACHETS.
- How to take HOT TODDY™ ADULT SACHETS.
- Possible side effects.
- How to store HOT TODDY™ ADULT SACHETS.
- 6. Contents of the pack and other information.

1. What HOT TODDY™ ADULT SACHETS is and what it is used for

HOT TODDY™ ADULT SACHETS may assist in soothing the symptoms associated with colds and flu, such as cough and congestion.

2. What you need to know before you take HOT TODDY™ ADULT SACHETS Do not take HOT TODDY™ ADULT SACHETS:

 if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of HOT TODDY™ ADULT SACHETS (see What HOT TODDY™ ADULT SACHETS contains).

Warnings and precautions

Take special care with HOT TODDY™ ADULT SACHETS:

- if you have a bleeding disorder;
- if you are having any surgical procedure done. You should stop taking HOT TODDY™ ADULT SACHETS two weeks before an operation;
- if you have inflammation of your stomach or you have a stomach ulcer.

Children and adolescents

Do not give HOT TODDY™ ADULT SACHETS to children under the age of 18 years. HOT TODDY™ ADULT SACHETS is not indicated for use in children.

Other medicines and HOT TODDY[™] ADULT SACHETS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

HOT TODDY™ ADULT SACHETS with food, drink and alcohol

See section 3 (How to take HOT TODDY™ ADULT SACHETS).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking HOT TODDYTM ADULT SACHETS.

Safety and efficacy of HOT TODDY™ ADULT SACHETS during pregnancy and breastfeeding have not been established. Do not use HOT TODDY™ ADULT SACHETS if you are pregnant or breastfeeding your baby.

Driving and using machines

Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how HOT TODDYTM ADULT SACHETS affects you.

HOT TODDY™ ADULT SACHETS contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking HOT TODDY™ ADULT SACHETS.

HOT TODDY[™] ADULT SACHETS contains egg yellow colourant (containing quinoline yellow, salt and sunset yellow)

HOT TODDYTM ADULT SACHETS contains egg yellow colourant which may cause allergic reactions.

3. How to take HOT TODDY™ ADULT SACHETS

Do not share medicines with any other person.

Always take HOT TODDY[™] ADULT SACHETS exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults: Take 1 sachet three times a day with half a glass of hot water. Stir the mixture. If necessary, add cold water. It is advisable to drink the solution as hot as possible, without burning your mouth.

If you have the impression that the effect of HOT TODDY™ ADULT SACHETS is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

HOT TODDY™ ADULT SACHETS can be taken with or without food.

If you take more HOT TODDY™ ADULT SACHETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining HOT TODDY™ ADULT SACHETS with you so the doctor will know what you have taken.

4. Possible side effects

HOT TODDY™ ADULT SACHETS can have side effects.

Not all side effects reported for HOT TODDYTM ADULT SACHETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HOT TODDYTM ADULT SACHETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking HOT TODDY™ ADULT SACHETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to HOT TODDY™ ADULT SACHETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following: Side effects occurring frequently:

- redness of your skin;
- stomach pain or discomfort;
- burping;
- indigestion;
- heartburn
- nausea (feeling sick) or vomiting (being sick);
- diarrhoea (runny, loose stool).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of HOT TODDYTM ADULT SACHETS.

5. How to store HOT TODDY™ ADULT SACHETS

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the sachet / carton.
- Use sachet immediately once opened. Do not store an unsealed / opened sachet.
- Store in the original packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information What HOT TODDY™ ADULT SACHETS contains

Each sachet contains:

The active substances are:

Siphonochilus aethiopicus (Schweinf.) B.L. Burtt (African ginger)	300 mg
Hedera helix L. (Ivy extract)	30 mg
[leaf, 5:1 extract providing 150 mg of dried herb equivalent]	
Ascorbic acid (Vitamin C)	100 mg
Citrus limon (L.) Osbeck (Lemon)	5 mg
[fruit, 10:1 extract providing 50 mg of dried herb equivalent]	
Honey	25 mg
Zingiber officinale Roscoe (Ginger)	2,5 mg
[root, 4:1 extract providing 10 mg of dried herb equivalent]	
Cinnamomum cassia (L.) J. Presl. (Cinnamon)	2,5 mg
[bark, 4:1 extract providing 10 mg of dried herb equivalent]	

The other ingredients are citric acid anhydrous (E330), egg yellow colourant (containing quinoline yellow (E104), salt and sunset yellow (E110)), ginger flavour, lemon flavour, maltodextrin (E1400), menthol flavour, silicon dioxide anhydrous (E331), sucrose and Sweetener A100 (containing acesulfame K and sodium cyclamate (E952)).

What HOT TODDY™ ADULT SACHETS looks like and contents of the pack

Beige powder with dark speckles and characteristic lemon and menthol taste.

After dilution: Yellow solution with a lemon and menthol odour.

HOT TODDY[™] ADULT SACHETS are packed in 6,4 g printed foil sachets, packed in an outer carton. Pack size(s): 4 or 8 sachets.

Holder of certificate of registration

Brunel Laboratoria (Pty) Ltd 1 Van Tonder Street Sunderland Ridge Centurion 0157 info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

The Professional Information for HOT TODDY™ ADULT SACHETS is available on http://www.brunel.co.za/hot-toddy-2/ or can be requested from the contact details above.

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